

<b>Case Number:</b>	CM13-0070768		
<b>Date Assigned:</b>	01/08/2014	<b>Date of Injury:</b>	07/18/1994
<b>Decision Date:</b>	04/22/2014	<b>UR Denial Date:</b>	12/20/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/26/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 51-year-old female with a date of injury of July 18, 1994. The covered body regions include the bilateral shoulders, bilateral knees, and psychologic/mood disorder. The patient carries diagnoses of lumbar disc degeneration, lumbar fusion, knee arthritis, prior knee arthroscopic surgeries, cervical disc degeneration, and previous shoulder arthroscopy. The patient current medication as of a progress report on December 12, 2013 indicates that she is taking Norco, fentanyl patch, Lidoderm, Celexa, docusate, omeprazole, tizanidine, trazodone, and Zantac. A utilization review determination denied the request for tizanidine, and partially certified the request for Fentanyl patch, Norco, and gabapentin. The stated rationale was that "overall there are no documented changes in complaints or functioning with treatments given." The reviewer recommended measurable improvements of changes in activities of daily living.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

#### **FENTANYL PATCH 50MG #10: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 43.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Page(s): 76-80.

**Decision rationale:** The Chronic Pain Medical Treatment Medical Guidelines on pages 76-80 state the following criteria for the ongoing use of opioids, including: "Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)" The most relevant progress report for this patient is a note on date of service December 12, 2013. There is documentation that the Fentanyl patch is "helpful." However, there is no documentation of objective functional improvement, and furthermore there is no indication that monitoring for aberrant behavior has taken place in the form of urine drug screens or checking the narcotic database. Given this, this request is recommended for non-certification and the utilization review determination is upheld.

**NORCO 10/325MG #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74-82.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Page(s): 76-80.

**Decision rationale:** The Chronic Pain Medical Treatment Medical Guidelines on pages 76-80 state the following criteria for the ongoing use of opioids, including: "Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)" The most relevant progress report for this patient is a note on date of service December 12, 2013.

There is documentation that the Fentanyl is "helpful," but the sentence describing the Norco contains a blank and it is likely the provider intended to state the Norco is helpful as well. However, there is no documentation of objective functional improvement, and furthermore there is no indication that monitoring for aberrant behavior has taken place in the form of urine drug screens or checking the narcotic database. Given this, this request is recommended for non-certification and the utilization review determination is upheld.

**TIZANIDINE 4MG #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine Page(s): 67.

**Decision rationale:** The Chronic Pain Medical Treatment Medical Guidelines on page 66 states the following regarding tizanidine: "Tizanidine (Zanaflex®®, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007)" Regarding the request for tizanidine, there is documentation in a progress note on date of service December 12, 2013 that the tizanidine is "helpful." There is no description of the chronicity of use of anti-spasm medication. The California Medical Treatment and Utilization Schedule only recommend muscle relaxants for short term use. A review of the submitted documentation is to include a preceding progress report that comments on the patient's pain regimen. Given the lack of documentation, this request is recommended for non-certification.

**GABAPENTIN 300MG #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 17.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin under Anti-Epileptic Drugs Page(s): 18-19.

**Decision rationale:** "Gabapentin (Neurontin®®, Gabarone®, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT [randomized controlled trial] concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a

more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study." In the case of this injured worker, there is lack of documentation of the efficacy of gabapentin. The most relevant progress report on date of service December 12, 2013 fails to comment on the clinical efficacy of this medication. Given this lack of documentation, this request is recommended for non-certification.